STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
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Final Report

Genetic Privacy, Discrimination, and Research in Washington State: Findings, Conclusions, and Recommendations of the Washington State Board of Health Genetics Task Force

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Executive Summary

The Washington State Legislature recognized a need to evaluate state policies regarding genetic privacy and discrimination, and to assess the potential effect of new policies on privacy, civil rights, and research and development into the use of deoxyribonucleic acid (DNA) to promote public health, safety, and welfare. This recognition led to the inclusion of language in the state's biennial budget—Engrossed Substitute Senate Bill (ESSB) 6153, Section 220.8—directing the State Board of Health (SBOH) to convene a broad-based task force charged with reviewing "the available information on the potential risks and benefits to public and personal health and safety, and to individual privacy, of emerging technologies involving human DNA."

Pursuant to this mandate, the Board established the Genetics Task Force (GTF) in October 2001. The 22-member volunteer GTF, which comprised representatives from a variety of professional, consumer, and public organizations, held five public meetings between January 2002 and September 2002. During this time the Task Force received and evaluated information pertaining to four areas identified by the Legislature: a) the incidence of discriminatory actions based upon genetic information; b) strategies to safeguard civil rights and privacy related to genetic information; c) remedies to compensate individuals for inappropriate use of genetic information; and d) incentives for further research and development in the use of DNA to promote public health, safety, and welfare.

The findings of the Task Force reflect the complexity of issues surrounding genetic privacy and discrimination based on genetic information. Overall, the Task Force recognized that research and development into new DNA-based technologies is proceeding at a rapid pace, and it is providing knowledge and many potentially beneficial tools to medicine and public health. These technologies are also creating opportunities for researchers, insurers, and employers to use genetic information in ways previously unavailable.

The Task Force examined existing Washington State policies that may address genetic privacy and discrimination. The GTF sought to determine if the policies adequately protect privacy and civil rights and provide sufficient incentives to promote the progress of potentially beneficial research and development. The GTF discovered that there are many facets to this question including, but not limited to, the debate over genetic exceptionalism and the absence of significant quantitative data regarding privacy violations and discriminatory actions associated with the use of genetic information.

In general, Task Force members agreed that identifiable genetic information is personal information and the privacy of personal information is paramount regardless of who holds the information. Furthermore, the absence of quantitative data on the incidence of privacy violations or discriminatory actions does not necessarily mean that these acts do not occur. The Task Force cannot determine the extent to which this finding may be an indication that: 1) victims or witnesses of discrimination do not report such incidents out of fear, embarrassment, or ignorance of wrongdoing; 2) authorities do not recognize such incidents because of a lack of active surveillance, oversight, or enforcement of program policies or existing anti-discrimination laws; 3) the public, health care providers, and researchers lack knowledge of existing reporting mechanisms and appropriate avenues for recourse; and/or 4) these events have not occurred in Washington State.

The Task Force also agreed that existing laws provide some protection against privacy violations and discrimination based on genetic information. However, the members concluded that these laws provide the greatest protection for genetic information obtained, used, or stored within the health and medical care systems. The Task Force identified gaps and ambiguities in existing laws that leave open the opportunity for privacy and civil rights violations to occur by not providing sufficient protection for genetic information held outside of the health and medical care systems.

In addition, the Task Force considered remedies to compensate individuals for the misuse of their genetic information. The GTF found that recourse and remedies for privacy or civil rights violations consist of reporting violations to administrative or oversight agencies and pursuing actions against perpetrators in court. Most laws reviewed by the GTF that are aimed at protecting an individual's civil rights and privacy provide for civil or criminal penalties in cases of wrongdoing. However, the Task Force noted that there is a dearth of case law specific to the misuse of genetic information on which it might draw conclusions about remedies individuals claiming privacy violations or discrimination based on genetic information may receive. In contrast, case law provides examples of remedies for wrongdoing by health care providers, employers, or insurance companies in matters related to the broad issues of privacy and civil rights. Therefore, the GTF found that avenues for obtaining compensation or punishing violators exist within the current legal tort system, but they may not explicitly apply to instances of privacy violations or discrimination involving genetic information.

Finally, the GTF evaluated incentives for further research and development in the use of DNA to promote public health, safety, and welfare. Incentives may include policies that address perceived risks of discrimination or privacy violations in order to assure that potential research subjects are not dissuaded from participating in research studies. Overall the Task Force found that incentives to continue genetic research and development exist in the form of funding and opportunities created by industry, academic, and government research agendas.

Based on the findings and conclusions outlined in this report, the GTF developed the following recommendations for the Washington State Legislature regarding genetic privacy and discrimination and incentives to promote further research and development in the use of DNA to promote public health, safety, and welfare. Some of these recommendations call for new legislation.[1] Nineteen members of the 22-member GTF endorsed this report; the remaining three members did not issue position statements regarding the content presented herein. However, at least two of them were very active participants throughout the entire process and are believed to be generally supportive of this report.

[1] Discussions of the GTF's conclusions and logic that supports these recommendations can be found in the "Conclusions and Recommendations" section of the report, beginning on page 26.

Incidence of discriminatory actions based upon genetic information

Recommendations[2]

1.1. Reports of **genetic testing** should remain in medical records and receive the **same protection as other sensitive medical information**.

1.2. Support and **authorize funding** where necessary for efforts **to educate** consumers, research subjects, researchers, health care providers, employers, and insurers **about how genetic information** derived from genetic testing, as part of medical information, **can be used**, the concepts and consequences of anonymity in research, **and** the reporting and other **mechanisms available to those who believe they have been discriminated against**. These efforts should include: 1) providing information to consumers, research subjects, researchers, health care providers, employers, and insurers about existing laws and penalties for violations regarding the privacy and appropriate use of genetic information; 2) establishing a graduate program in genetic counseling at the University of Washington to address the current and future needs of the state's population.[3]

1.3. Change The **Washington State Law Against Discrimination (Chapter 49.60 RCW) to explicitly include "genetic information"** in the list of characteristics that receive protection under the law. The GTF recommends that "genetic information" be defined as "Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination."[4]

Strategies to safeguard civil rights and privacy related to genetic information

Recommendations[5]

2.1 **Adopt in rule the existing administrative policies protecting** the privacy of **newborn screening specimens** and other tissue samples **held by the state**.

2.2 Create policy to **make all research in** the State of **Washington involving genetic information** obtained from human subjects **subject to** the **standards** that are in place **for federally funded and/or regulated** human subjects **research**.[6]

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[2]Minority Recommendation: Prof. Philip Bereano proposed that the State create a policy to destroy tissue samples in the forensic database after DNA profiling is complete.

[3] Robin Bennett and Dr. Wylie Burke recommended that this effort include education for health care providers and genetic testing laboratories regarding the professional ethic against presymptomatic testing of children under age 18 years for untreatable adult onset disorders, including such children being placed for adoption. Julie Sanford Hanna stated that the onus of making the decision to conduct presymptomatic genetic testing on children under age 18 years should be primarily on health care providers and not on laboratory personnel because health care providers order tests and are more likely to develop a relationship with the patient and his or her family. Thus, she suggested that the educational and policy efforts in this area should focus on health care providers.

[4] Mellani Hughes, JD dissented from this recommendation on the grounds that WSHRC and EEOC both interpret the WLAD and the ADA to be applicable in cases of employment or other discrimination based on genetic information, rendering additional language in RCW 49.60 unnecessary, particularly when there is little evidence of such discrimination. Dr. Peter Byers also dissented from this recommendation on the grounds that current statutes and codes appear to provide the same coverage, existing policies restrict access to genetic information, and this change may lead to unanticipated problems. In addition, Dr. Nancy Fisher and Dr. Peter Byers felt that the proposed definition of genetic information is too broad to have power and value in the context of the statute.

[5] Minority Recommendation: Prof. Philip Bereano and Ty Thorsen recommended that the State enact legislation that explicitly defines genetic discrimination, genetic information, and privacy rights of individuals with respect to genetic information.

2.3 Where current law permits the **collection** or use **of genetic information by employers or insurers**, state law **should require informed consent** from the individual for collection, storage, disclosure, and any use of such information. Uses of such information should be restricted to those purposes for which it is collected or purposes required by law. The individual providing the information shall receive the results of any tests conducted by or for the recipient of the information.

2.4 Revise Chapter 26.04 RCW to **remove the ban on first cousin marriage**.

Remedies to compensate individuals for inappropriate use of genetic information

Recommendations[7]

3.1 **Designate a centralized agency to** receive and **act on** reports of **discrimination** based upon genetic information **or violations of privacy involving genetic information**.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Recommendations

4.1 Given the limited nature of the data provided by testing conducted for the criminal DNA database, incentives for research using this resource are not warranted.

4.2 **Ensure that state policy requires** that in all research involving genetic information from individuals, **explicit voluntary consent or assent** be obtained or waived as detailed in applicable law and regulations.[8]

4.3 **Invite** all **stakeholders to participate in** any process to create **policies addressing** the use of **genetic information in research**.

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[6] Dissent: Mellani Hughes, JD dissented from this recommendation on the grounds that insufficient evidence was received about whom this type of policy would affect.

[7] Minority Recommendation: Prof. Philip Bereano and Ty Thorsen recommended that the State pass legislation that protects the privacy of genetic information, defines and outlaws genetic discrimination, and provides avenues for redress when violations are proven.

[8] See also recommendation number two under "Strategies to safeguard civil rights and privacy related to genetic information." If all research conducted in the state were subject to federal law this concern would be addressed.

Introduction

The 2001–03 Washington State biennial operating budget, enacted as Engrossed Substitute Senate Bill 6153 in June 2001, included a proviso (Sect. 220.8) for the State Board of Health (SBOH) to convene a broad-based task force to "review the available information on the potential risks and benefits to public and personal health and safety, and to individual privacy, of emerging technologies involving human DNA." The proviso directed the task force to report its findings, conclusions, and recommendations no later than October 2002. The mandate required the task force to consider evidence brought to it on the following four issues:

1) the incidence of discriminatory actions based upon genetic information;
2) strategies to safeguard civil rights and privacy related to genetic information;
3) remedies to compensate individuals for inappropriate use of genetic information; and
4) incentives for further research and development in the use of DNA to promote public health, safety and welfare.

In response to the legislative mandate, SBOH formed the Genetics Task Force (GTF). The GTF comprised 22 members and met five times over a nine-month period between January and September 2002. During this period, the GTF received and deliberated over information from experts and interested parties on privacy, discrimination, and research with respect to genetic information.

Information received by the GTF included analyses of existing state and federal legislation and regulations including but not limited to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rules, the Americans with Disabilities Act (ADA), the Uniform Health Care Information Act (Chapter 70.02 RCW), the Washington Law Against Discrimination (WLAD) (Chapter 49.60 RCW), and Office of the Insurance Commissioner (OIC) rules. The GTF also received presentations regarding Washington State's newborn screening program and related privacy policies, the history of genetics-related legislation in Washington State, the historical practices of eugenics, legislative efforts in other states, and the potential effect of privacy and anti-discrimination policies on ongoing and future genetic research endeavors in Washington. This report summarizes the findings, conclusions and recommendations of the GTF.

Background

Legislative History

The Washington State Legislature considered 25 different drafts of various genetics-related legislation between January 1998 and March 2002. Appendix A presents a summary of the legislation considered during this time period. The scope of the proposed legislation varied significantly and included topics such as criminal DNA databases, health insurance practices, informed consent requirements, prohibitions against the misuse of genetic information, statutory definitions of terms such as "genetic information" or "health care information," the formation of review committees and/or task forces, and genetic testing practices. During this time period, few of the proposed bills related to genetic privacy and discrimination issues passed out of the Legislature. The debates surrounding proposed privacy and anti-discrimination legislation predominantly focused on two areas: 1) the need to protect the privacy rights of individuals and to prevent the use

of genetic information to adversely discriminate against individuals in insurance or employment; and 2) the effect of such legislation on genetic research and development and the biotechnology industry in Washington. One effort to reach a resolution to these debates was the establishment of the Joint Select Committee on DNA Identification in 1999. This Committee included four members each from the House and Senate. The Committee expired in July 2000 without agreeing upon recommendations for further legislative action.

Subsequent legislative activity aimed at collecting information regarding the need for and impact of genetic privacy and anti-discrimination legislation included Section 220(8) of the 2001–03 Washington State biennial operating budget described previously.

ESSB 5207, passed in March 2002, is the most recent legislative action taken by the Washington State Legislature with respect to genetic privacy. ESSB 5207 amended the Uniform Health Care Information Act (Chapter 70.02 RCW) to include a person's deoxyribonucleic acid (DNA) and identified sequence of chemical base pairs in the definition of "health care information."

Defining the Scope of the Genetics Task Force

In response to the legislative directive in ESSB 6153, SBOH approved a work plan for the GTF in October 2001.[9] The work plan defined the scope of the GTF in a manner consistent with the legislative budget proviso. The Board asked the GTF to consider the potential of genetic information to advance scientific knowledge and improve health care practice in the context of privacy and discrimination concerns and to consider possible regulations regarding the use of and access to genetic information. The work plan included consideration of the collection, storage, and sharing of genetic information within the health and medical care systems as well as the use of genetic information in the context of health, life, and disability insurance and employment as balanced against the risk of harm to scientific research and development. The scope of the GTF excluded issues related to stem cell research and cloning.

Selecting GTF Members

SBOH invited experts and interested persons from the following interests to serve on the GTF: state and local public health, public and private purchasers of medical care, health insurance carriers, primary care physicians, pathology and laboratory medicine, genetic counselors, hospitals, genetic ethicists, institutional review boards, research geneticists, trial attorneys, medical research institutions, civil rights advocates, privacy advocates, citizens who have undergone genetic testing, parents whose children have been helped by genetic testing, the biotechnology industry, and experts in privacy laws and rules such as HIPAA. Some of the individuals invited to serve were presently or previously involved with existing SBOH or Washington State Department of Health (DOH) genetics committees such as the Newborn Screening Advisory Committee, the Prenatal Screening Advisory Committee, and the DOH Genetic Services Advisory Committee. Other members represented relevant professional societies and associations. Table 1 is a list of GTF members and their affiliations.[10]

[9] A copy of the Work Plan is available at http://www.doh.wa.gov/SBOH/Priorities/Genetics/genetics.htm.

[10] Robert Miyamoto expressed concern that the Task Force membership represented a bias toward health and related health issues. Further, he felt that the amount of time required to fully participate excluded individuals who are not

professionally involved in the issues considered by the Task Force. Mr. Miyamoto stated that those members who were professionally involved were able to influence the process more than those who had to take vacation and outside time from work in order to participate and devote time to the issues. He believes that this dynamic affected the outcome of the report.

Table 1 GTF Members

Robin Bennett, MS, CGC
University of Washington
Medical Genetics
Representing: Genetic Counselors

Philip L. Bereano, JD
Professor
University of Washington
College of Engineering
Department of Technical Communication
Founding Board Member Council for Responsible Genetics
Vice-President, Washington Biotechnology Action Council
Representing: The American Civil Liberties Union

Wylie Burke, MD, PhD
Professor and Chair
University of Washington
Department of Hisotry and Medical Ethics
Representing: Genetics and Medical Ethics

Peter Byers, MD
Professor
University of Washington
Department of Medicine
Department of Pathology
Representing: Research Geneticists

Maureen Callaghan, MD
The Middleton Foundation, Inc.
Representing: Washington State Medical Association

Howard Coleman
Chairman, CEO, and Chief Development Officer
Genelex Corporation
Representing: Biotechnology Industry

Amanda DuBois, JD
Washington State Trial Lawyers Association
Representing: Trial Attorneys

Joe Finkbonner, R.Ph., MHA
Board of Health Member
Washington State Board of Health
Representing: Washington State Board of Health

Nancy Fisher, MD, MPH, RN
Medical Director
Regence Blue Shield
Representing: Health Insurance Carriers

Maxine Hayes, MD, MPH
State Health Officer
Department of Health
Representing: State Public Health

Vicki Hohner, MBA
Senior Consultant
Fox Systems, Inc.
Representing: HIPAA Privacy Experts

Mellani Hughes, JD
Governmental Affairs Counsel
Association of Washington Business
Representing: Private Purchasers of Medical Care

Linda Lake
Chair of the Washington State Board of Health
Chair of the Genetics Task Force
Representing: Washington State Board of Health

Helen McGough
Director of Human Subjects Division
University of Washington
Representing: Institutional Review Boards

Robert Miyamoto
Associate Director for Applied Research and Technology
University of Washington
Applied Physics Laboratory
Representing: Parents of children helped by genetic testing

Suzanne Plemmons, RN, MN, CS
Director, Family and Community Health
Director, Bremerton-Kitsap Health
Representing: Local Public Health

Ree Sailors
Executive Policy Advisor
Office of the Governor
Representing: Public Purchasers of Medical Care

Julie Sando
Representing: Citizens who have undergone genetic testing

Julie Sanford-Hanna, PhD
President, DOH Genetic Advisory Committee
Director, Clinical Cytogenetics
Sacred Heart Medical Center, Department of Lab Medicine
Representing: Pathologists or Laboratory Medicine

C. Ronald Scott, MD
Professor
University of Washington
Department of Pediatrics
Representing: Medical Research Institutions

Brenda Suiter
Director, Rural and Public Health Policy
Washington State Hospital Association
Representing: Hospitals

Ty Thorsen
Product Development Manager - Cisco Systems
Board Member American Civil Liberties Union - Washington
Representing: Privacy Advocates, ACLU-WA

Methods

The GTF met five times over the course of nine months: January 3, 2002; February 25, 2002; April 12, 2002; June 25, 2002; and September 4, 2002. All meetings were open to the public. Three meetings served as opportunities to hear from experts or interested parties on specific topics. Table 2 summarizes the topics covered at these meetings. GTF staff supplemented information received at the meetings with literature and legislative research and consultation with legal advisors. Staff presented research summaries in the form of the Genetic Privacy and Genetic Discrimination Matrix for Washington State and the Genetics Task Force Working Glossary, which are included with this report as Appendices C and D, and meeting summaries, which are available at http://www.doh.wa.gov/SBOH/Priorities/Genetics/genetics.htm.

The GTF reviewed the charge in the budget proviso and the scope of work as detailed in the work plan at the January 3, 2002 meeting. State Senator Rosa Franklin and Representative Al O'Brien attended this meeting and spoke about the Legislature's intentions when drafting the charge to the GTF. Their comments provided a context in which the GTF could place the legislative mandate and helped to narrow the focus of the Task Force to specific areas of interest to the Legislature. Additional information received at the January 3, 2002 meeting included: an overview of previously proposed genetics-related legislation in Washington State; an introduction to the fundamentals of genomic science and the potential ethical, legal, and social implications of scientific advancements related to human genetics; an introduction to federal and state privacy laws and regulations such as HIPAA, the Governor's Executive Order on Privacy (EO 00-03), the Uniform Health Care Information Act (Chapter 70.02 RCW), and the Patient's Bill of Rights (SB 6199); an introduction to the Washington State Newborn Screening Program; and an overview of Institutional Review Board (IRB) practices and policies.

The GTF convened its second meeting on February 25, 2002. Prior to the meeting, the GTF published a notice of its intent to receive information about evidence of privacy violations concerning the unauthorized release or misuse of genetic information. It issued press releases, held public hearings, solicited testimony on the SBOH Web site, and provided several avenues for the public to submit oral, written, or electronic testimony. Representatives from the Washington State Office of the Insurance Commissioner (OIC) and the Washington State Human Rights Commission (WSHRC) presented analyses of regulations administered by each agency and explained how existing regulations may pertain to issues of genetic discrimination in insurance and employment. The OIC and WSHRC representatives also provided information on the incidence of genetic discrimination as reported to the OIC and WSHRC. Other presentations at that meeting included an overview of historical eugenics practices, an introduction to the potential misuses of genetic information, an introduction to the practices and policies of health insurers, and summaries of genetic privacy and anti-discrimination legislation in other states.

Table 2 Meeting Topics January 2002 through April 2002

Date	Topic	Presenters
January 3, 2002	• Overview of Work Plan • Review of legislative history • Legislative context for charge to the GTF • Introduction to genomics • Newborn Screening Program • HIPAA and genetic privacy • Washington State Health Care Information Act • Institutional Review Board policies and guidelines	• Roberta Wines • Joan Mell, JD • Senator Franklin, Representative O'Brien • Dave Eaton, PhD, Wylie Burke, MD, PhD • Debra Lochner-Doyle • Vicki Hohner • Joan Mell, JD • Helen McGough
February 25, 2002	• Overview of pertinent insurance laws and policies • Overview of genetic privacy and genetic discrimination • Historical perspectives on eugenics • Introduction to health insurance practices and policies • Review of genetics related privacy and discrimination legislation in other states • Overview of the effects of genetics privacy legislation on research in Oregon • Evidence of genetic discrimination and privacy violations in Washington state	• Jon Hedegard • Philip Bereano, JD • Nancy Fisher, MD • Nancy Fisher, MD • Mary Ferguson, PhD • Roberta Wines • Mary Clogston
April 12, 2002	• Academic/Basic Science Panel • Public Health Panel • Biotechnology Industry Panel	• Kenneth Thummel, PhD, Jonathan Tait, MD, PhD • Karen Edwards, PhD, Maxine Hayes, MD, MPH, Amy Klein, MPH • Eric Earling, Steve Gilbert, PhD, Bruce Montgomery, MD

The third GTF meeting occurred April 12, 2002 in conjunction with the Henry Art Gallery's Gene(sis) exhibit. The GTF heard from three panels of researchers on the topics of academic/basic science research, public health research, and private industry-sponsored research. The panelists provided perspectives on the multitude of uses for genetic information in research and the development of genetic technologies to promote public health, safety, and welfare. Panelists also addressed issues of oversight by local and federal agencies including requirements to protect human subjects through informed consent procedures, monitoring, and the maintenance of data security. In addition, GTF members used the meeting to develop a strategy for drafting conclusions and recommendations based on their findings from the previous meetings. Task Force members formed four subcommittees to draft reports from the perspective of different circumstances for obtaining and/or using genetic information. Table 3 lists the topic and members of each subcommittee.

Table 3 Genetics Task Force Subcommittees

Subcommittee Title	Subcommittee Chair	Subcommittee Members
SC1: The use of genetic information for health care including the diagnosis of symptomatic patients, reproductive decision-making, and predictive genetic testing for low penetrant genetic disorders	C. Ronald Scott, M.D.	Robin Bennett, M.S.,C.G.C., Julie Sanford-Hanna, Ph.D., Robert Miyamoto, Ph.D., Maureen Callaghan, M.D.
SC2: State mandated DNA collection and testing	Maxine Hayes, M.D., M.P.H.	Philip Bereano J.D., Brenda Suiter, Howard Coleman, Suzanne Plemmons, R.N., M.N., C.S.
SC3: The use of genetic information for research purposes	Peter Byers, M.D.	Helen McGough, Philip Bereano, J.D., Amanda DuBois, J.D., Vicki Hohner
SC4: The use of genetic information for social purposes such as insurance and employment	Mellani Hughes, J.D.	Ty Thorsen, Wylie Burke, M.D., Ph.D., Nancy Fisher M.D., M.P.H., R.N., Joe Finkbonner

The GTF reviewed a draft of the final report and received comments on the draft from four community advocacy groups at the September 4, 2002 meeting. Significant changes to the conclusions and recommendations section resulted from the discussion at this meeting. Collectively, the members of the Task Force revised several of the conclusions and recommendations presented in the subcommittee reports and added some recommendations not included in the subcommittee reports. Subsequently, staff made revisions to the report and provided a second draft to the GTF members for review. Nineteen Task Force members endorsed the revised report; some members' endorsements were contingent upon minor changes and/or the inclusion of additional statements of their opinions. See Appendix B for a summary of the members' comments. Three members did not submit position statements regarding the report.

The Subcommittees

The GTF organized into four subcommittees to clearly delineate some of the different circumstances in which an individual's genetic information may be obtained and used:

1) The use of genetic information for health care including:
    a) the diagnosis of symptomatic patients;
    b) reproductive decision-making; and
    c) predictive genetic testing for low penetrant genetic disorders;
2) State mandated DNA collection and testing including:
    a) newborn screening; and
    b) criminal DNA databases;
3) The use of genetic information for research purposes; and
4) The use of genetic information for social purposes such as health, life, and disability insurance and employment.

Reports from the Subcommittees are available in Appendix E to this report. Following is a brief description of the approach taken by each Subcommittee and the issues considered by the members.

Subcommittee One: The use of genetic information for health care including: a) the diagnosis of symptomatic patients; b) reproductive decision-making; and c) predictive genetic testing for low penetrant genetic disorders

Subcommittee One analyzed the information presented to the GTF from the perspective of the health and medical care system. For the purposes of their deliberations, the members of Subcommittee One adopted the following definition of "genetic test": the analysis of DNA, RNA, chromosomes, proteins, or other gene products to detect disease-related genotypes, mutations or karyotypes for clinical purposes or phenotype prediction.

Genetic information is used in a variety of ways within the health and medical care system. For example, physicians use it for the medical diagnosis of symptomatic patients. This generally occurs through either chromosome or DNA analysis conducted in licensed medical laboratories. Physicians may request DNA analysis of blood samples from children with mental retardation who are suspected of having Fragile X syndrome, from males with symptoms of Duchenne muscular dystrophy, from persons with a clotting disorder, or from adults with muscle and neurologic changes suggestive of a genetic condition. The introduction of DNA testing has simplified the medical diagnosis of these and many other conditions that in the past may have involved anesthesia, muscle biopsies, or expensive and laborious testing by other means.

DNA technology is a very powerful tool in reproductive medicine and physicians and counselors use genetic information to assist people with reproductive decisions. In general, the technology is used for this purpose in two ways: 1) identification of asymptomatic pregnant couples at risk for having a newborn with a severe genetic disease; and 2) utilization of DNA technology in subsequent pregnancies in families that have previously given birth to a child with a genetic disorder. Both situations offer parents and health care providers the opportunity to prevent or prepare for the birth of a child affected by a genetic disorder.

A third way that health care providers use genetic information is for the predictive identification of genetic risk factors associated with late-onset diseases. In certain instances, DNA testing can identify genetic predisposition to a disease prior to the onset of clinical symptoms. This type of testing may be used in three different situations. First, young children at high risk for developing a serious disorder for which intervention may be available can be tested for a genetic predisposition to the disorder before symptoms arise. Predictive genetic testing may be offered to infants who have a sibling with cystic fibrosis, male children in families with Duchenne muscular dystrophy, or children born into a family at high risk for a genetic disease for which therapy is available.

The second category of predictive genetic testing is more complicated. A number of disorders exist in which clinical symptoms do not present until adulthood. DNA technology has the potential to identify individuals at risk for some of these conditions at any age prior to the onset of symptoms. Genetic testing can predict some of these disorders with a finite probability prior to

the onset of symptoms if an individual carries a particular form of a gene associated with the disorder. Examples include the predilection for breast cancer in individuals who carry an abnormality of the BRCA1 or BRCA2 genes, or the predilection for neurological degeneration around the age of 40 in individuals with an abnormality of the Huntington disease gene. In the case of a woman with a strong family history of breast cancer, it may be appropriate to screen that woman using DNA testing to determine her genetic risk of developing breast cancer. Screening allows for early detection or prevention of breast cancer in a woman with mutations in BRCA1 or BRCA2. In the case of Huntington disease, an autosomal dominant condition, children of an affected individual are at 50 percent risk for developing the condition in adulthood, but there exist no medical strategies for treatment or cure. In this case, DNA testing may be appropriate for medical information and for personal decision-making on lifestyle changes.

A third use of predictive genetic testing is the testing of children under 18 years of age for medical conditions that may present in adulthood; again the examples of testing for susceptibility to breast cancer or Huntington disease is relevant. Many health care providers consider it unethical to test children for adult onset disorders prior to the age when they can give informed consent. This opinion applies to children born into families who are at increased risk for adult onset diseases or children being placed for adoption with no known prior risk factors.

Subcommittee Two: State mandated DNA collection and testing including: a) newborn screening; and b) criminal DNA databases

The report presented by Subcommittee Two is based on two instances of state law that require the collection and testing of an individual's DNA. First, the subcommittee considered Chapter 70.83 RCW and Chapter 246-560 WAC concerning the State's Newborn Screening Program. State law (Chapter 70.83 RCW) requires "… screening tests of all newborn infants before they are discharged from the hospital for the detection of phenylketonuria and other heritable or metabolic disorders leading to mental retardation or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices." Other disorders for which testing is done include congenital hypothyroidism, congenital adrenal hyperplasia, and hemoglobinopathies. SBOH regulations (Chapter 246-650 WAC) adopted pursuant to this statute direct hospitals to obtain blood specimens from infants and send them to the State Public Health Laboratory for testing. The specimens consist of a few drops of blood that are absorbed and dried onto a filter paper form.

The second instance concerns the collection of DNA from felons and certain other criminals and the maintenance of the information gleaned from the sample in a database. The recently amended state law titled DNA Data Base (Chapter 43.43 RCW), requires that "Every adult or juvenile individual convicted of a felony, stalking … harassment … or communicating with a minor for immoral purposes … must have a biological sample collected for purposes of DNA identification analysis …." These samples are tested according to certain specifications outlined in federal law and are retained by the Forensic Services Bureau of the Washington State Patrol. The statute restricts uses to "… identification analysis and prosecution of a criminal offense or for the identification of human remains or missing persons" or "… improving the operation of the [DNA

identification] system." The statute also allows the State Patrol to submit DNA test results to the Federal Bureau of Investigation combined DNA index system (CODIS) which is authorized under the DNA Identification Act of 1994 (42 U.S.C.A§14132).

Subcommittee Three: The use of genetic information for research purposes

Subcommittee Three examined the collection and use of genetic information for research purposes. Research in human genetics has become one of the most exciting areas of study in the last decade, bringing with it both promise and concern. The technological innovations that accompanied the thrust to provide the genetic map and sequences of the human genomes have been increasingly applied more recently to the examination of human variation. This variation is being viewed both from the point of view of population differences and from the perspective of individual identification for forensic purposes as well as for the identification of both known disease causing mutations and a search for variations in DNA sequences that may be associated with susceptibility to common diseases such as heart disease, hypertension, diabetes, stroke, and mental illness, among others.

The interest in studies of human genetics exists for several reasons. First, humans have an intense curiosity about who we are and the history of our origins. The analysis of the origins of modern humans and their migrations has provided a picture of the relationships among all humans that emphasizes common features. Second, the identification of the more than 30,000 genes that encode proteins and regulatory molecules has provided the substrate for complex approach to understanding the intricacies of human development in both health and disease. Technological advances have made it possible to work with more than one gene at a time and to define how genetic "systems" work. The area of greatest interest to researchers is the third, the detailed analysis of the genes that are involved in promoting health and disease. This type of research occurs in several settings including the academic research community, where it is often supported by federal or other charitable funds, and private industry, where it is usually supported by funds from the private enterprise such as pharmaceutical companies. The activities in this domain are significant in a clinical setting for the diagnosis and confirmation of specific genetic disorders.

These research activities warrant consideration as they raise questions about the manner in which research findings are used and the extent to which findings about individuals that emanate from research done in publicly versus privately funded environments are subject to the same types of regulation. There is already a complex network of regulatory provisions for research funded or regulated through federal sources that contain explicit guidelines on the protection of subjects and the protection of the information that results from these studies. Issues such as how these data could be treated and how they form part of the medical information about an individual can arise with the publication of the these data and the release to individuals of information from the studies.

Subcommittee Four: The use of genetic information for social purposes such as health, life and disability insurance and employment

Subcommittee Four considered the use of genetic information for social purposes. The members of this subcommittee evaluated the potential for employers and insurance companies to use an individual's genetic information. Issues considered by this subcommittee included whether employers could obtain and use genetic information to make employment decisions and what constitutes appropriate use of genetic information in life, health, and disability insurance.

Findings

The GTF adopted the following findings related to the four areas specified in the legislative mandate.

Incidence of discriminatory actions based upon genetic information in Washington State

The GTF solicited testimony from the Washington State Human Rights Commission (WSHRC), the Office of the Insurance Commissioner (OIC) and the DOH Genetic Services Section (GSS) regarding evidence of discriminatory actions based upon the use of genetic information. Representatives from WSHRC and the OIC testified that neither agency has received reports or complaints from citizens of Washington State with respect to adverse discriminatory actions resulting from an employer's or insurance company's knowledge of an individual's genetic information. A representative from the DOH GSS provided a log of 38 inquiries and complaints received between November 20, 1991 and November 16, 2001. The Task Force found that three of these incidents represented cases in which family history or genetic status may have been used to adversely discriminate against an individual. The rest of the complaints were based on the need for additional education and/or genetic counseling resources.

The GTF received no additional information about documented cases of adverse discriminatory actions based on genetic information obtained or used for diagnostic genetic testing, reproductive decision-making, predictive genetic testing, newborn screening, criminal DNA databases, or research. However, members agreed that the possibility of discrimination based on genetic testing, and predictive genetic testing in particular, exists. In addition, fear of discrimination may prevent individuals from participating in research, seeking clinical genetic tests, or disclosing genetic information. With regard to the use of DNA technology for prenatal or preconception testing, the Task Force found that there is little, if any, risk of discrimination because testing is always voluntary, done with informed consent and test results are maintained within the patient's private medical record. Task Force members reaffirmed the right of individuals to seek genetic counseling and appropriate genetic testing when they are at risk for transmitting a serious genetic disorder and the rights of children born with genetic conditions or at risk for developing genetic conditions to be free from discrimination because of any immediate or future disability.

Other findings of the Task Force related to the incidence of discriminatory actions based on genetic information are based on a review of the legislation, policies, and procedures associated with the Newborn Screening Program, the criminal DNA database, research activities, insurance industry policies and practices, and employment practices. The GTF found that no active

surveillance systems are in place to proactively monitor the use of genetic information created and stored within the scope of the state's Newborn Screening Program or the criminal DNA database or for insurance or employment purposes. In contrast, the GTF found that formal reporting and monitoring systems are in place for research activities. Reporting systems allow research subjects to report perceived abuses that occur during the course of a research study to the principal investigator, IRB, or a federal oversight agency such as the Food and Drug Administration. Internal and federal oversight agencies actively monitor researchers and IRBs; however, research that is not regulated by federal human subjects standards such as 45 CFR 46 (the Common Rule) and 21 CFR 50 may not have such monitoring systems in place.

The risk of discrimination based on predictive genetic information led the Task Force to consider the possibility of discrimination based on information from DNA research studies regarding predispositions to disease. In some cases, this information might be disclosed to research subjects. The GTF found that individuals may be protected from some forms of misuse of this information by WAC 284.43.720, which prohibits health plans from treating genetic information as a health condition in the absence of a diagnosis of the condition related to such information.

With respect to the incidence of discrimination based upon genetic information used for social purposes such as insurance and employment, the Task Force found that state agencies do not systematically survey people or make proactive efforts to collect information regarding discrimination based on genetic information; however, agencies such as DOH, OIC, and WSHRC have passive reporting systems in place for receiving complaints.

In addition, the Task Force examined the potential risks of adverse discrimination based upon genetic information in insurance and employment and found that statistical tables used by life insurance companies are based on estimates of life expectancy at a given age. These estimates account for the population-based occurrence of genetic conditions that may affect life expectancy. Furthermore, information about an individual's family history is a common and allowable request for some types of insurance coverage and broader definitions of genetic information may include family history. The GTF also found that health, life, and disability insurers view genetic information as a category of health care or medical information and that some state laws and industry practice disallow the use of health information (including genetic information) to set rates for, cancel, or not renew a consumer of health insurance. Specifically, Chapter 48.18.480 RCW prohibits unfair discrimination in insurance matters and WAC 284.43.720 states that "health carriers may not reject health plan applicants and may not limit or exclude plan coverage for any reason associated with health risk or perceived health risk except for the imposition of a preexisting condition exclusion as permitted in this chapter." Disability and life insurance may use health information to underwrite a policy but state law and/or industry practice prohibits the use of health information to cancel or not renew an existing consumer of these policies. Table 4 and the Genetic Privacy and Genetic Discrimination Matrix for Washington State in Appendix C summarize some of the laws and policies governing insurance practices in Washington State.

Table 4 Summary specific insurance policies and practices in Washington State

Issue	Summary
Health insurance (preexisting conditions)	Individual, small-, and large-group health insurance plans may contain a waiting period of up to nine months for coverage of preexisting conditions[11], but genetic information cannot be considered a health condition unless it is accompanied by a diagnosis of the condition.[12]
Long-term care, Medicaid supplemental, and disability insurance (preexisting conditions)	Preexisting condition limitations vary for long-term care, Medicare supplemental, individual or group disability insurance. The use of genetic information to define a preexisting condition may not be prohibited by law for some long-term care, Medicare supplemental, individual, or group disability insurance plans.[13]
Life insurance	In general, life insurance companies can use health care information, including genetic information, to deny coverage or to set initial rates; there are no laws preventing the use of preexisting conditions in life insurance underwriting. However, regulations do prohibit cancellation of a policy because of health conditions that emerge after issuance. Life insurance rates are term-based and policies may be periodically re-classified.
Property and casualty insurance	Property and casualty insurance plans generally do not consider health care information when enrolling clients, however the use of health care information for these plans is not specifically prohibited. An insurer using health care information to deny, cancel, or set rates must justify the action.[14]

Regarding the risk of adverse discrimination in employment based on genetic information, the GTF found that the WSHRC and the Federal Equal Employment Opportunities Commission (EEOC) interpret the WLAD (Chapter 49.60 RCW) and the ADA to be applicable in cases of employment or other discrimination based on genetic information. However, the scope and interpretation of these laws with respect to genetic information has not been tested in the courts.

WSHRC writes rules and oversees the implementation of the WLAD. A representative from WSHRC testified to the GTF that WSHRC rules are broad enough to allow the agency to investigate and take action against claims of discrimination based upon genetic information if they arise. WLAD prohibits employers from refusing to hire, discharging or barring, or discriminating against any person in compensation based on any sensory, mental, or physical handicap.[15] The scope of the WLAD also includes circumstances surrounding real estate, public accommodation, credit, and insurance practices.

[11] RCW 48.43.012; RCW 48.43.025 (1); RCW 48.43.025 (2)
[12] WAC 284-43-720(3)
[13] WAC 284.54.200; 284.66.063; WAC 284.50.320
[14] Robert Miyamoto suggested that similar uses of health care information by life insurance companies should also require justification.
[15] Additional State legislation regarding protection from discrimination in employment includes Chapter 49.44.010 RCW, which prohibits "blacklisting" by employers. This statute prohibits an employer from willfully or maliciously making a statement with the intention of preventing a person from securing employment.

The Federal EEOC writes rules pertaining to and oversees the implementation of the ADA. The EEOC rules address the retention, storage, and use of employees' health information. The EEOC considers the scope of the ADA to include genetic tests and genetic information and believes that employers who discriminate against employees on the basis of predictive genetic tests "regard" the employees as having a disabling impairment and are therefore acting in violation of the ADA.[16] The ADA states that before making an offer of employment, an employer may not ask job applicants about the existence, nature, or severity of a disability; applicants may be asked about their ability to perform job functions. Under the ADA, a job offer may be conditioned on the results of a medical examination, but only if the examination is required for all entering employees in the same job category and the medical examination is job-related and consistent with business necessity.

The GTF notes that neither the WSHRC interpretation of the WLAD or the EEOC interpretation of the ADA with respect to the applicability of these statutes to cases involving discrimination based upon genetic information have been tested in court. Furthermore, the GTF found that recent Supreme Court decisions suggest a more narrow scope and interpretation of the ADA.[17]

Overall, the Task Force agreed that receiving very few reported cases of adverse discriminatory actions based upon genetic information does not prove that such incidents do not occur more frequently. The few documented cases of potential discrimination received by the GTF may not represent all such cases. The GTF found that the lack of evidence of reported cases does not necessarily indicate that there is no risk of adverse discrimination based upon genetic information. Some argue that the perceived risk of discrimination may explain the low numbers of reported cases of discrimination and represent a need for education about how genetic information can be legally obtained, used, or disclosed, and how abuses of such procedures may be reported.

Strategies to safeguard civil rights and privacy related to genetic information

The GTF received information about several state and federal strategies that may protect individuals' civil rights and privacy with respect to their genetic information. The Task Force found that these existing laws, regulations and policies provide substantive protection with respect to an individual's privacy and civil rights relating to his or her genetic information especially if that information is held within a medical record or is considered health care information. However, the GTF identified some ambiguities and/or weaknesses in existing legislation and noted specific gaps and/or lack of protection against certain privacy or civil rights violations with regard to genetic information held outside of the health and medical care system.

Strategies at the state level include the Uniform Health Care Information Act (RCW 70.02), the Patient's Bill of Rights (SB 6199), Release of Records for Research (Chapter 42.48 RCW), the Governor's Executive Order on Privacy (EO 00-03), and various legislation including WAC 284.04.500, WAC 246.320.205 (2) (5), Chapter 43.105.310 RCW, and Chapter 51.28.070 RCW

[16] EEOC Compliance Manual, section 902.8, available online at http://www.eeoc.gov/docs/902cm.html.
[17] Board of Trustees of the University of Alabama v. Garrett, 531 U.S. 356 (2001); Albertson's, Inc. v. Kirkingburg, 527 U.S. 555 (1999); Sutton v. United Airlines, 527 U.S. 471 (1999); Murphy v. United Parcel Service, 527 U.S. 516 (1999); Toyota Motor Manufacturing, Kentucky, Inc. v. Williams, 122 S.Ct. 681 (2002)

that regulate the privacy of health care information held by health insurers, hospitals, and state agencies. Specifically, the Task Force found that state and federal laws protect the privacy of medical records. For example, the Washington State Legislature recently amended the definition of "health care information" in the Uniform Health Care Information Act (Chapter 70.02 RCW) by passing ESSB 5207 in March 2002. The statutory definition of "health care information" now includes DNA. Furthermore, the GTF received evidence indicating that newborn blood spots obtained and used in the Newborn Screening Program and the data associated with these spots fit within the definition of health care information and fall under the purview of this state law. In addition, the Task Force reviewed a draft of the DOH Newborn Screening Specimen Policy that sets specific privacy standards for the newborn blood spots collected and stored by the state. Appendix F includes a summary of this policy and a copy of the draft document.

In addition, the Uniform Health Care Information Act prohibits the unauthorized disclosure of identifiable health care information by a health care provider for research purposes unless such disclosure meets IRB approval (70.02.050 1(g)). To the extent that genetic information generated in the course of research is considered health care information, the Uniform Health Care Information Act also protects the privacy of this information. GTF members noted, however, that there is a question as to whether some research data is considered health care information. The Uniform Health Care Information Act does not protect the privacy of health care information held outside of the health care system.

Other state laws address the privacy and civil rights of research subjects and individuals seeking or holding an insurance policy. For example, the Release of Records for Research statute (Chapter 42.48 RCW) provides parameters under which a state agency may disclose individually identifiable personal information for research purposes and under which researchers may further disclose such information. Additionally, the Patient's Bill of Rights (SB 6199) and WAC 284-04-500 mandate that health carriers and insurers adopt policies and procedures that conform administrative, business, and operational practices to protect an enrollee's right to privacy or right to confidential health care services granted under state or federal laws. Another strategy adopted by Washington State is the Governor's Executive Order on Privacy (EO 00-03), which protects the privacy of all readily identifiable personal information held by a state agency or contractor. EO 00-03 prohibits state agencies, employees or contractors from disclosing identifiable personal information to any party without legal authority. Finally, various pieces of legislation such as WAC 246.320.205 (2) (5), Chapter 43.105.310 RCW, and Chapter 51.28.070 RCW mandate that hospitals and state agencies such as the Department of Labor and Industry maintain specific standards of privacy.

In addition to protections afforded to health information, the Task Force noted that existing safeguards exist to protect the privacy of genetic information collected and stored as part of the criminal DNA database system.[18] Uses for this information are restricted in both state and federal law. Furthermore, the segments of DNA tested in this program are not associated with any known medical condition or disease.

[18] Professor Bereano noted that additional safeguards may be warranted in order to adequately protect genetic information in the tissue samples collected for the criminal DNA database system.

Federal laws that aim to protect an individual's privacy and civil rights with respect to their genetic information include the HIPAA Privacy Rules, EEOC Rules and the ADA, and the Protection of Human Subjects (45 CFR 46 and 21 CFR 50) regulations. The HIPAA Privacy Rules, to which covered entities must comply by April 2003, apply to health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically. Health care information is defined within HIPAA as "any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual or the provisions of health care to an individual or the past, present, or future payment for the provision of health care to an individual." A report published by the National Conference of State Legislatures (NCSL) states, "this definition includes currently manifested diseases of genetic origin as well as genetic information, since such information "relates to" a possible future medical condition."[19]

The HIPAA Privacy Rules grant patients specific control over the release and use of their health information. A previous version of the Rules required physicians to obtain the consent of patients before releasing private health information for purposes related to health care treatment, payment and health care operations. Under these rules, providers were not required to provide care if the patient did not consent to the release of information for these purposes.[20] However, an August 2002 revision by the Department of Health and Human Services (HHS) changed this rule. Under the new rule, a patient's consent is no longer required for the release of health information for the purposes of treating patients, paying bills and carrying out various health care operations. Disclosures for other purposes require patient authorization but a physician cannot deny a patient care in the absence of such authorization.[21] With respect to research, the new HIPAA Privacy Rules allow researchers to use a single combined form to obtain informed consent for participation in research and authorization to use or disclose protected health information for such research. The new rules also specify requirements relating to a researcher obtaining an IRB waiver of authorization by streamlining waiver criteria to more closely follow the requirement of the "Common Rule" (45 CFR 46), which governs federally funded research.

HIPAA does not apply to individual or small-group (defined as fewer than 50 individuals) health plans and the regulations do not apply to entities outside of the health care system other than contractors who obtain identifiable information as part of their responsibilities to the health plan or health care provider. Furthermore, there is no active surveillance or monitoring system that ensures compliance with these regulations. More restrictive state laws preempt the HIPAA Privacy Rules and separate privacy mandates exist at both the state and national level that protect information held by the criminal justice system, schools, public health agencies, mental health and substance abuse providers, and other entities.

Other federal laws such as the ADA, 45 CFR 46 and 21 CFR 50/56 protect individuals from unauthorized disclosure or use of their health information by employers and researchers. The ADA and rules adopted by the EEOC define the type of information an employer can request and

[19] NCSL "Genetics Policy and Law: A Report for Policy Makers", September 2001
[20] Ibid
[21] Ibid

use in making employment decisions. Federal regulations such as 45 CFR 46 and 21 CFR 50/56 regulate the conduct of research involving human subjects. 45 CFR 46 applies to all research involving human subjects that is conducted, supported, or otherwise subject to regulation by any federal department or agency including research conducted outside the United States. This regulation also requires that research that is neither conducted nor supported by a federal department or agency, but is subject to regulation as defined in Sec 46.102(e) must be reviewed and approved by an IRB.[22] In addition, some private funding sources may require that researchers comply with 45 CFR 46. Still other privately funded researchers may voluntarily abide by 45 CFR 46 regardless of their funding or regulatory source. The Task Force noted that genetic research activities conducted without federal financial support, in facilities that have not voluntarily adopted the federal protections, and that do not involve FDA-regulated test articles are not required to conform to and follow legal requirements and standards established for the involvement of human subjects in research.

Research regulated by the Food and Drug Administration (FDA) is subject to the purview of 21 CFR 50 and 21 CFR 56, which specify requirements for the protection of human subjects in research and the circumstances under which IRB review is required. Researchers and IRBs undergo routine inspections to verify compliance with these federal regulations; they also have extensive reporting responsibilities to parent agencies. In addition, researchers, IRBs and federal oversight agencies accept and investigate complaints from research subjects regarding violations of these regulations.

According to 45 CFR 46, different research study designs require different levels of informed consent. For example, research using "anonymized" biological samples from which all information that could identify the individuals from whom they were obtained has been removed may not require the informed consent of the individuals. However, research that involves samples linked to information from which the donor can be identified almost always requires the consent of the individual who originally provided the information or biological sample. Certificates of confidentiality[23] constitute another level of protection available to research subjects. Researchers may apply for a federal certificate of confidentiality to protect research data from court-ordered disclosures under most circumstances.

With respect to strategies to safeguard an individual's privacy and civil rights in matters outside of the health care system or research arena, the Task Force examined Washington's law on domestic relations (RCW 26.04.020), which prohibits marriage between persons closer in kin than second cousins. GTF members presumed that the law was based at least in part on the previously widely held belief that the probability of related individuals bearing children with congenital defects due to genetic abnormalities was high. Recent scientific studies, however show that the risk of such harm is low and therefore, the GTF found that there is little biological basis for these restrictions.[24] It is legal to marry a first cousin in many other states and the 79th National Conference of Commissioners on Uniform State Laws and Proceedings (1970) recommended striking cousin marriage restrictions. Therefore, it appears to the GTF members that from a scientific perspective, the law banning marriage between first cousins is unnecessary.

[22] 45 CFR 46 Sec 46.101 (a) and Sec 46.101 (a)(2)
[23] For more information about Federal Certificates of Confidentiality see: http://grants1.nih.gov/grants/policy/coc/
[24] Bennett et al., Journal of Genetic Counseling, 2002;11:97-119

Based on this information, the Task Force found that at present the scope and interpretation of existing laws provide substantive protection of an individual's privacy and civil rights regarding genetic information. The Task Force noted, however, that the extent to which these laws encompass genetic information varies, and in some situations may be poorly defined and untested. Furthermore, the scope and interpretation of some of these laws may change over time and with increasing demands on the legal system to apply these laws to situations in which the central issue is the use or disclosure of genetic information. GTF members noted that the privacy of health care information and medical records seem to be well protected by existing legislation; however, gaps and ambiguities in existing laws leave open the opportunity for privacy and civil rights violations to occur in areas outside of the health and medical care systems.

Remedies to compensate individuals for inappropriate use of genetic information

The Task Force found that avenues for obtaining compensation or punishing those who engage in genetic discrimination or the invasion of genetic privacy exist within the current legal tort system. Many of the strategies reviewed in the previous section include clauses pertaining to compensation or legal action in cases where inappropriate use of genetic information occurs. In most circumstances, claims of privacy or civil rights violations must be reported to an oversight agency and/or brought before a court of law. Specifically, the Task Force found that state and federal agencies such as WSHRC, the OIC, OCR, and the EEOC have the authority to investigate claims and levy fines against violators. Table 5 summarizes the provisions that may allow for compensation for victims and/or legal action against those who inappropriately use genetic information.

Task Force members found that legal avenues available to individuals who are victims of the misuse of their genetic information consist of reporting violations to administrative and/or oversight agencies and pursuing actions against perpetrators in court. Most of the laws reviewed by the GTF that are aimed at protecting an individual's civil rights and privacy provide for civil and/or criminal penalties in cases of wrongdoing.

Table 5 Summary of legislation that provides penalties and/or remedies to compensate individuals for inappropriate use of genetic information

Law	Allowable Remedies
Uniform Health Care Information Act (Chapter 70.02 RCW)	Action can be brought against violators. Relief is limited to actual damages and attorney fees and other expenses of bringing the action. The individual must state the claim within two years after the cause of action is discovered.
Release of Records for Research (Chapter 42.48.050 RCW)	Unauthorized disclosure of personally identifiable information by a researcher who obtained the information from a state agency is a gross misdemeanor subject to fines up to $10,000 for each violation.
Washington Law Against Discrimination (Chapter 49.60 RCW)	This statute does not provide for specific compensation, however, the WSHRC receives and investigates complaints and may hold hearings and subpoena witnesses. If WSHRC efforts fail to remedy the problem, the matter may be sent to the Attorney General for litigation before the Administrative Law Judge. In addition, individuals may sue for discrimination under this statute.
Patient's Bill of Rights (ESSB 6199)	Individuals may sue violators and the parties involved may request an independent review process.
HIPAA Privacy Rules	The Health and Human Services Office for Civil Rights (OCR) relies on reports and formal complaints regarding violations and investigates claims of violations and seeks informal resolutions. If an informal resolution cannot be achieved, OCR may apply civil monetary fines or work with the Justice Department to seek criminal prosecution. Civil monetary penalties are $100 per violation and capped at $25,000 per year. Criminal fines range from $50,000 to $250,000 and prison terms range from one to 10 years.
Americans with Disabilities Act	The EEOC relies on individuals to report violations, as there is no active monitoring system. Reported violations are investigated and in cases of wrongdoing, the EEOC may sue violators in court. Individuals may also file suit against those in violation of the ADA.[25]
The Protection of Human Subjects regulations (45 CFR 46 and 21 CFR 50)	IRBs monitor compliance with federal and local regulations. Federal oversight agencies may also conduct periodic inspections. IRBs rely on internal and external reviews and inspections of research proposals and reporting of violations by research subjects or others. The FDA inspects entities regulated by the FDA for compliance with FDA regulations. Penalties include fines, suspension of research activities and suspension of federal funding for research involving humans. In addition, victims of violations may sue researchers and institutions that house research.
The federal DNA Identification Act (1994)	Establishes criminal penalties for individuals who knowingly violate privacy protection standards and provides that access to the federal system is subject to cancellation if privacy requirements are not met. The Act does not provide individuals with specific remedies for the inappropriate use of their genetic information.

[25] Professor Bereano noted that it is unlikely that employees would be aware of the misuse of their genetic information and therefore unlikely to report violations.

Incentives for further research and development in the use of DNA to promote public health, safety and welfare

Representatives from academic/basic science research, public health, and the biotechnology industry appeared before the GTF and discussed the current and future contributions of genetic research to public health, safety and welfare and the regulations, practices, and methods pertaining to different types of genetic research. The panelists informed the Task Force that the potential benefits of genetic research and emerging genetic technology include: achieving a better understanding of many aspects of human biology; the development of tools for medical care including: disease prevention, diagnosis, and treatment; expansion of genetic testing as an aid for the reproductive health of mothers and fetuses; and the development of genetic tests that will identify individuals at risk for developing adult onset diseases for which interventions may be available such as diabetes, hypertension, renal disease, and cardiovascular disease. Previous and ongoing research has resulted in the development of numerous genetic tests. However, the full benefits and clinical applicability of some of these tests may not yet be realized because knowledge about the significance of test results with respect to outcomes and other consequences is lacking for many of them. Ongoing and future genetic research such as studies aimed at associating genotypes with phenotypic profiles may be important to medical and public health knowledge in this area as well as to the development of screening programs, education and intervention programs, and therapies. The Task Force noted, however, that the issuing of patents for specific DNA sequences may interfere with basic research and the useful development of genetic tests for clinical purposes by barring other researchers from certain areas of inquiry and by elevating the prices charged for genetic tests.

Access to research subjects and biological material is important for studies investigating the relationship between genotype and phenotype and the continued development of genetic tests, technology and pharmaceuticals. Under current policies, research involving human subjects may be subject to different oversight requirements depending on the source of funding and/or regulation or level of anonymity involved in the data collection process. For some study designs, anonymous research samples, for which informed consent may not be required, are adequate. Other studies require the use of identifiers to match clinical data with genotype data. The latter type of research most often requires informed consent from, and therefore access to, the individuals from whom the samples and clinical data were derived. Several presenters noted that fear of discrimination is a reason that people may choose not to participate in genetic studies.

Regarding incentives for further research and development in the use of DNA to promote public health, safety and welfare, representatives from the biotechnology industry commented that their research and business endeavors are sensitive to changes in policy that may affect their ability to conduct research. The Task Force found from other testimony that academic/basic science, public health and biotechnology researchers receive adequate incentives to conduct genetic research. Adequate incentives also exist within the medical community for researching and developing uses of DNA to promote predictive testing of late onset diseases. For example, there is funding available for and ongoing research on predicting individuals at risk for developing diabetes, hypertension, renal disease, and cardiovascular disease. In addition, government and private funds exist to expand the use of genetic testing in reproductive medicine. Incentives at the state level include the availability of newborn screening specimens for research as long as

appropriate safeguards are followed. The Task Force found that, overall, incentives to continue genetic research and development exist in the form of funding and opportunities created by industry, academic, and government research agendas but policies that address the perceived risk of discrimination provide an additional incentive.

Conclusions and Recommendations

The following conclusions and recommendations reflect the opinions of the Genetics Task Force regarding Washington State policies related to individuals' civil rights and privacy with respect to their genetic information. These conclusions and recommendations are based on the GTF's findings and specific conclusions and recommendations proposed by the four subcommittees. In some cases, the Task Force adopted the conclusions and recommendations brought forth by each subcommittee; however, some conclusions and recommendations changed after discussion among the whole group.

Incidence of discriminatory actions based upon genetic information

With respect to the incidence of discriminatory actions based upon genetic information, the Task Force reached several conclusions. First, based on reports from the Office of the Insurance Commissioner (OIC), the Washington State Human Rights Commission (WSHRC), and the DOH Genetic Services Section (GSS), the GTF concluded that very few documented cases of discrimination have been reported in Washington State. The evidence presented to the Task Force by the OIC, WSHRC, and DOH GSS did not indicate that there is a widespread problem regarding the use of genetic information for social purposes such as employment or health, life, or disability insurance. However, reported incidents may not represent all such events and while the reported rate of discrimination appears low, the risk of discrimination based upon genetic information may still exist. For example, genetic testing may place individuals at risk for genetic discrimination should such information exceed the bounds of the medical care system. In addition, gaps in protection exist that may leave research subjects vulnerable to the misuse of genetic information obtained in research if that information would have to be reported by the subject to insurers, employers, or others who may make decisions on the basis of that information and use it in an adverse fashion against the individual. In contrast, genetic information that remains part of an individual's private medical record and is limited in its use by third parties presents little risk of discrimination.

Second, fear of discrimination may prevent individuals from pursuing medically indicated genetic testing, participating in research studies, and disclosing relevant genetic information when appropriate. Given the potential benefit of genetic testing to an individual's health and the contributions of genetic research to improving public health, safety, and welfare, the GTF concluded that reducing the impact of this fear is important. Increased awareness of the meaning of specific genetic information and of both the appropriate uses and the means for reporting inappropriate uses of genetic information may encourage people to utilize genetic technology.

Lastly, the GTF concluded that regulatory interpretations of existing state and federal laws as well as industry practices and policies, provide some protection against discrimination in health, life, and disability insurance and may provide protection against employment discrimination or

other privacy and civil rights violations. However, if the language in the law on which the regulation is based does not explicitly refer to genetic information, the interpretation is left open to challenge in court and could potentially be overturned.

Recommendations[26]

1.1 Reports of genetic testing should remain in medical records and receive the same protection as other sensitive medical information.

1.2 Support and authorize funding where necessary for efforts to educate consumers, research subjects, researchers, health care providers, employers, and insurers about how genetic information derived from genetic testing, as part of medical information, can be used, the concepts and consequences of anonymity in research, and the reporting and other mechanisms available to those who believe they have been discriminated against. These efforts should include: 1) providing information to consumers, research subjects, researchers, health care providers, employers, and insurers about existing laws and penalties for violations regarding the privacy and appropriate use of genetic information; 2) establishing a graduate program in genetic counseling at the University of Washington to address the current and future needs of the state's population.[27]

1.3 Change The Law Against Discrimination (Chapter 49.60 RCW) to explicitly include "genetic information" in the list of characteristics that receive protection under the law. The GTF recommends that "genetic information" be defined as "Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination."[28]

Strategies to safeguard civil rights and privacy related to genetic information

In general the Task Force felt that the protection of individuals' civil rights and privacy with respect to their genetic information is paramount. The members recognized that many of the benefits of DNA technology depend on the exchange of personal, sensitive information between an individual and a health care provider, researcher, or even an insurer. This exchange must be

[26]Minority Recommendation: Prof. Philip Bereano proposed that the state create a policy to destroy the tissue samples in the forensic database after the DNA profiling is complete.

[27] Robin Bennett and Dr. Wylie Burke recommended that this effort include education for health care providers and genetic testing laboratories regarding the professional ethic against presymptomatic testing of children under age 18 years for untreatable adult onset disorders, including such children being placed for adoption. Julie Sanford Hanna stated that the onus of making the decision to conduct presymptomatic genetic testing on children under age 18 years should be primarily on health care providers and not on laboratory personnel because health care providers order tests and are more likely to develop a relationship with the patient and his or her family. Thus, she suggested that the educational and policy efforts in this area should focus on health care providers.

[28] Mellani Hughes, JD dissented from this recommendation on the grounds that WSHRC and EEOC both interpret the WLAD and the ADA to be applicable in cases of employment or other discrimination based on genetic information, rendering additional language in RCW 49.60 unnecessary, particularly when there is little evidence of such discrimination. Dr. Peter Byers also dissented from this recommendation on the grounds that current statute and codes appear to provide the same protection, existing policies restrict access to genetic information, and this change may lead to unanticipated problems. In addition, Dr. Nancy Fisher and Dr. Peter Byers felt that the proposed definition of genetic information is too broad to have power and value in the context of the statute.

uninhibited by fears of privacy violations or unfair discrimination; individuals must be assured that their information, once voluntarily shared, will be kept confidential and not be misused.[29]

Based on its examination of existing strategies to safeguard civil rights and privacy related to genetic information, the GTF concluded that existing strategies aimed at protecting the privacy of health care information substantively protect genetic information as long as it remains in the health or medical care system. Many of the laws regulating the privacy of health or medical records are unambiguous and they appropriately prohibit the misuse of health care information including genetic information. One area of the health care system that may need additional safeguards is the protection of newborn screening specimens and other biological samples collected and stored by Washington State. The GTF noted that this program, along with the criminal DNA database, represent two instances of state-mandated DNA collection and testing; the members caution that any infringement on an individual's rights to free choice regarding their DNA/genetic information is perilous and to be avoided in all but the most specific and compelling circumstances found in these two programs. Furthermore, because the state mandates testing of all newborns, it must protect the privacy of the samples it collects and stores.

The GTF also concluded that adequate safeguards exist at the federal level to protect information collected, used, or generated in the course of federally funded or regulated research. However, the federal standards for human subjects research may not apply to all genetic research. For example these standards may not apply to research that is not federally funded or regulated. Therefore, appropriate monitoring or oversight systems may be lacking in some settings.

Under some circumstances insurers and employers may request or obtain specific health care information about an individual. The GTF concluded that in these circumstances, the individual providing the information may not be informed of the reasons for collecting, testing, storing, or further disclosing such information. Uninformed collection, use, or disclosure of personal health information is a violation of the individual's right to privacy.

Finally, with respect to privacy and civil rights related to genetic information, the GTF concluded that the Washington State law prohibiting the marriage of first cousins (RCW 26.04.020) may not be justified on a scientific basis and restriction of marriage between cousins can be construed as genetic discrimination.

Recommendations[30]

2.1 Adopt in rule existing administrative policies protecting the privacy of newborn screening specimens and other tissue samples held by the state.

2.2 Create policy to make all research in the State of Washington involving genetic information obtained from human subjects subject to the standards that are in place for federally funded and/or regulated human subjects research.[31]

[29] HIPAA Privacy Rule, Standards for Privacy of Individually Identifiable Health Information, Federal Register, December 28, 2000.

[30] Minority Recommendation: Prof. Philip Bereano recommended that the State enact legislation that explicitly defines genetic discrimination, genetic information, and privacy rights of individuals with respect to genetic information.

[31] Dissent: Mellani Hughes, JD dissented from this recommendation on the grounds that insufficient evidence was received about whom this type of policy would affect.

2.3 Where current law permits the collection or use of genetic information by employers or insurers, state law should require informed consent from the individual for collection, storage, disclosure, and any use of such information. Uses of such information should be restricted to those purposes for which it is collected or purposes required by law. The individual providing the information shall receive the results of any tests conducted by or for the recipient of the information.

2.4 Revise Chapter 26.04 RCW to remove the ban on first cousin marriage.

Remedies to compensate individuals for inappropriate use of genetic information

Regarding remedies to compensate individuals for inappropriate use of genetic information, the GTF concluded that the existing tort system provides an avenue to compensate individuals for inappropriate use of genetic information. For example, the current legal tort system provides sufficient remedies if genetic information, including newborn screening specimens or data is misused in a health care setting or by a health care provider. With respect to genetic information that is collected and maintained for the criminal DNA database, federal law provides penalties for inappropriate use, but neither federal nor state law provide specific remedies to individuals beyond the current tort system. Furthermore, existing penalties for the violation of laws protecting the privacy and civil rights of individuals who provide genetic information for research purposes are adequate. However, in some cases, a specific oversight or regulatory agency charged with monitoring adherence to existing laws or receiving complaints about violations is lacking.

Recommendations[32]

3.1 Designate a centralized agency to receive and act upon reports of discrimination based upon genetic information or violations of privacy involving genetic information.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

The Task Force considered evidence presented to it regarding DNA research in Washington State and came to several conclusions. First, as genetic technologies improve through research, genetic testing will be introduced into the public health system as an adjunct to newborn screening for treatable genetic diseases to promote and assist the safety and welfare of young children detected with treatable disorders. Second, the development of testing for risk factors associated with multifactorial common diseases such as diabetes, hypertension, renal disease, and cardiovascular disorders may have a beneficial effect on public health policy and the welfare and safety of the population and therefore this research should be encouraged as a means of improving the health of the population. Third, at present, the development of genetic tests far outpaces the availability of information and personnel to interpret and apply the test results in a health care setting and the costs for making genetic testing available, as a result of costly research and development studies, may impede equitable availability of such resources to all segments of the population.

[32] Minority Recommendation: Prof. Philip Bereano recommended that the State pass legislation that protects the privacy of genetic information, defines and outlaws genetic discrimination, and provides avenues for redress when violations are proven.

Regarding incentives for further research and development on the use of DNA to promote public health safety and welfare the GTF concluded that cooperation from state programs may be important aspects of successful research programs, however some data retained by the state, such as data held within the criminal DNA database, is not appropriate for research. The GTF also concluded that Washington law must be such that biotechnology companies and other researchers want to locate or continue to remain and operate within the state. Policies that address the perception of the risk of discrimination associated with participating in a genetic research study may encourage research participation and provide an incentive for continued research and development. For example, protections provided by DOH policy, DSHS/DOH Human Subject Research Review Board policy, and the Release of Records for Research statute appear to be adequate to protect individuals without unnecessarily impeding research; requiring that all research comply with similar requirements such as informed consent may increase subject participation in research. Participation from all interested parties is essential for successful policy development.

Recommendations

4.1 Given the limited nature of the data provided by testing conducted for the criminal DNA database, incentives for research using this resource are not warranted.

4.2 Ensure that state policy requires that in all research involving genetic information from individuals, explicit voluntary consent or assent be obtained or waived as detailed in applicable law and regulations.[33]

4.3 Invite all stakeholders to participate in any process to create policies addressing the use of genetic information in research.

[33] See also recommendation number two under "Strategies to safeguard civil rights and privacy related to genetic information." If all research conducted in the state were subject to federal law this concern would be addressed.